DUC4

HIGH USERS OF β_2-AGONISTS: ARE MEDICAID RECIPIENTS BEING TREATED ACCORDING TO NATIONAL ASTHMA GUIDELINES?

Reddy P[1], Kelly E[1], Kophazi M[2], Geary E[3], Markelon J[1], Welter K[1]
[1]Pharmacy School, University of Connecticut, Storrs, CT, USA; [2]Health Information Design Inc., Auburn, AL, USA; [3]Connecticut Medicaid Department, Hartford, CT, USA

Studies have shown an association between increased use of β_2-agonists and risk of death. Little information is available on the appropriateness of asthma management in Medicaid populations although data suggest that Medicaid recipients experience higher healthcare utilization than non-Medicaid recipients. **OBJECTIVE:** To determine whether Medicaid's high dose β_2-agonists (HDB) users (>1 inhaler/month) are being managed according to National Institute of Health (NIH) asthma guidelines. **METHODS:** All Connecticut Medicaid pharmacy claims from April to December 1998 were examined. Subjects were included if they had an asthma diagnosis and were >5 years old. Subjects were excluded if they had chronic obstructive airway disease or a claim for ipratropium. The percent of HDB users receiving (1) no long-term controller (LTC = inhaled corticosteroid, theophylline, leukotriene modifier, mast cell stabilizer); (2) low doses of a LTC; (3) oral or nebulized β_2-agonists; (4) spacers or peak flow meters was determined. **RESULTS:** A total of 1596 profiles were included (42 ± 16 years, mean ± SD;79% female); 178 were excluded. Fourteen percent were HDB users; of these 24% did not have a claim for a LTC and 29% received low doses of a LTC. Oral or nebulized β_2-agonists claims were submitted by 34% of HDB users. Seven percent and 0% of HDB users submitted claims for spacers and peak flow meters, respectively. **CONCLUSION:** A high proportion of Medicaid asthma patients who are HDB users are not being managed according to recent NIH guidelines. Intervention programs designed to improve adherence to the guidelines will be developed.

Methodologic Issues/Advances MI

MI1

IDENTIFYING FACTORS ASSOCIATED WITH HIGH AND LOW COST ASTHMATICS: OPPORTUNITIES FOR DISEASE MANAGEMENT USING AUTOMATIC INTERACTION DETECTION

Boscarino JA, Zhao Z, Andrews KW, Sokol MC, Yao J, McGuigan KA, Gutierrez B, Refowitz, R
Merck-Medco Managed Care, Franklin Lakes, NJ, USA

Because the costs of treating asthmatic patients vary, we wanted to develop cost-effective health management strategies by identifying factors associated with high and low cost patients. **METHODS:** We integrated 24 months of medical and drug claims data for 89,245 individuals who had health benefits through two large US companies. Individuals were defined as asthmatics if they had two or more asthma medical or asthma drug claims over the first 12 months. 1,529 asthmatics (mean age = 38; females = 56%) were included in our study, after excluding those under age 5, over age 64, and COPD cases. We predicted costs in the second year based on first-year risk factors, using a recursive partitioning, Chi-squared Automatic Interaction Detection (CHAID) model. Predictor variables included: age, gender, region, member status, and 18 comorbidities based on the ICD-9 body-system method. **RESULTS:** We found higher average costs associated with asthmatics that had either circulatory disorders ($6,796, $P < 0.0001$) or cancers ($6,381, $P < 0.009$). However, asthmatics with circulatory and mental disorders ($20,035, $P < 0.0001$), digestive and nervous system disorders ($12,447, $P < 0.008$), and those with circulatory and nervous system disorders ($11,633, $P < 0.0001$) had the highest average costs. Conversely, the lowest costs were associated with 6–39 year old, male ($691, $P < 0.03$) and female ($1331, $P < 0.05$) asthmatics without comorbidities. The R^2 for the CHAID model was similar to stepwise regression (both approximately 12% for actual dollars and 30% for log dollars), and most of the variables selected were the same. **CONCLUSIONS:** Our analysis identified high and low cost asthmatic patients and may be useful in guiding future interventions. In order to reduce health care costs, for example, our study suggests asthmatics with concurrent circulatory and mental health disorders may warrant intense interventions, while younger male asthmatics without comorbidities may not.

MI2

THE NUMBER NEEDED TO TREAT APPROACH: EVALUATING THE CLINICAL RELEVANCE OF FEXOFENADINE IN SEASONAL ALLERGIC RHINITIS

Crawford B[1], Marquis P[2], Offord S[3]
[1]MAPI Values, Boston, MA, USA; [2]MAPI Values, Lyon, France; [3]Aventis Pharmaceuticals, Inc, Bridgewater, NJ, USA

The use of minimal important difference (MID) in quality of life assessment has grown recently in an effort to make measured changes more meaningful to the practicing physician. The use of MID, however, does not take into account the distribution of response, only the mean. **OBJECTIVE:** To examine the use of number needed to treat (NNT) in seasonal allergic rhinitis as a valid and more relevant approach to present data from clinical trials to physicians. **METHODS:** 538 subjects completed the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), a symptom questionnaire, and a self-reported change scale. These data were used to determine meaningful changes in the RQLQ and generate a 3 × 3 table to calculate the NNT. **RESULTS:** We examined data from the STAR study comparing fexofenadine, loratadine and pla-

cebo. The endpoint change in the RQLQ was stratified by self-assessed change to determine the NNT. This resulted in a NNT of 7.9 for fexofenadine, 63.5 for loratadine and 9.2 for fexofenadine versus loratadine. Thus, between 7–8 patients require treatment with fexofenadine for a patient to have a clinically meaningful improvement in quality of life while between 63–64 patients need to be treated with loratadine in order for one patient to obtain a significant improvement. Additional stratifications were examined to assess the effects of important differences on the NNT. Single digit NNT values, as seen with fexofenadine, strongly support the clinical relevance of the drug for improving patient quality of life. **CONCLUSIONS:** The NNT approach represents an understandable approach to presenting quality of life data that may be more meaningful to practicing physicians.

	Fexofenadine		
Loratadine	Improved	Unchanged	Deteriorated
Improved	0.6089	0.0915	0.0279
Unchanged	0.1691	0.0254	0.0077
Deteriorated	0.0580	0.0087	0.0027

MI3

RELIABILITY AND VALIDITY OF INTERNATIONAL PROSTATE SYMPTOM SCORE (I-PSS) FOR EARLY ASSESSMENT OF SYMPTOMS IN THE TREATMENT OF BENIGN PROSTATE HYPERPLASIA (BPH)

Singh A, Ashraf T, Verlinden MH
Abbott Laboratories, Abbott Park, IL, USA

The American Urology Association has developed a 7-item instrument I-PSS to measure the signs and symptoms of the disease process of BPH. The instrument was validated for a one-month and later for a weekly recall. Early and faster relief of symptoms are extremely important to patients. Therefore, we validated I-PSS for as early as 2 to 5 day response. **OBJECTIVE:** To test the reliability and validity of I-PSS administered between day two to five post-treatment. **METHODS:** I-PSS was administered at baseline and at day 2–5 after treatment as part of a double-blind study with 674 symptomatic BPH subjects. The patients were also administered a single item global question about their urinary condition. The test-retest reliability of the 2–5 day version was evaluated with intra-class correlation coefficient (ICC) between the two assessments. Internal consistency was computed with Cronbach's α. Guyatt's responsiveness statistics was estimated. Factor content of day 2 to 5 I-PSS was examined. The ability of I-PSS scores at days 2–5 to discriminate between improved and unimproved subjects was tested with receiver's operating characteristics curve (ROC) analysis. **RESULTS:** The average measure of ICC was found to be 0.7414. Cronbach's α was estimated to be 0.8093 (Barry et al 1995 reported 0.74 for ICC and 0.67 for Cronbach's α for one-week I-PSS). The Guyatt's responsiveness statistic was found to be −1.04 compared to −0.82 for a one-week version. Factor analysis revealed only one underlying factor (urinary symptoms) with an eigenvalue greater than one. The areas under ROC curve was 0.7635 (0.74 reported for a one-week version). **CONCLUSIONS:** The results conclude that I-PSS can be used to evaluate days 2–5 symptoms for BPH.

MI4

A FRAMEWORK FOR COST-EFFECTIVENESS ANALYSIS FROM CLINICAL TRIAL DATA

O'Hagan A[1], Stevens JW[2]
[1]University of Sheffield, Sheffield, UK; [2]AstraZeneca R&D Charnwood, Loughborough, UK

OBJECTIVES: The research objective was to develop a flexible Bayesian statistical framework for cost-effectiveness analysis using data from a clinical trial, and to illustrate the methodology in practical case studies. **METHODS:** The general methods of Bayesian statistical theory are used to develop the framework. For computation of results in case studies, simulation-based methods are used, including Markov chain Monte Carlo. **RESULTS:** A general framework is established, in which individual patient data arising in a clinical trial may be modeled using any appropriate probability models. Within the model, the true patient mean efficacy and true patient mean cost are represented as functions of the model parameters. Cost-effectiveness decisions are then based on inference about these true mean parameters for each of the two treatments under comparison in the trial. It is argued that appropriate decision indicators are whether the expected net benefit is positive, or the probability that net benefit is positive, with net benefit defined with reference to a specific threshold unit cost. When a range of unit costs must be considered, the relevant indicators are the break-even unit cost for expected net benefit, or the C/E acceptability curve (CEAC). Inference about these indicators is determined within the Bayesian statistical paradigm. Examples and case studies are presented illustrating the method with efficacy outcomes that are continuous, binary, ordinal or time-to-event, and with costs modeled as distributed normally, lognormally or nonparametrically. **CONCLUSIONS:** The Bayesian framework is demonstrated to be both a flexible and powerful tool for cost-effectiveness analysis from clinical trial data.